

## REMARKS

An Interview was conducted on August 20, 2009, where the patentability of product-by-process claims and the differences between the cited prior art and the present invention were discussed. Applicants' representative would like to thank the Examiner for her time and consideration in conducting the Interview.

Claims 1-16 are presented for examination, with Claims 1-5 and 7-16 being currently amended. The claims are amended to provide for consistent usage of terms and for grammatical clarity. Support for the amendments is found in the claims as originally filed and in the specification. For example, original Claim 1 recites that the titania solution is "obtained by" certain process steps. Claims such as Claim 4 are amended to change "prepared by" to "obtained by" in reference to the titania solution. Claims 4, 8, 10-13, and 14-16 are amended to remove redundancies, in light of the claims from which they depend. Claims 14-16 are amended to recite the correct preamble, according to the claims from which they depend. Claim 1 and 5 are amended to clarify the order of the process steps by correcting grammatical errors. The process steps are individually described in detail in sections B, C, and D of the specification and in the Examples. No new matter within the meaning of § 132 has been added by the amendment.

### Overview

The Office Action provided an overview of Applicants' invention. This overview misinterprets the process by which the claimed composite material is obtained. In particular, the titania solution is *not* obtained "by adding a solution consisting of acidic alcohol and water into an alcohol solution of titaniumtetraalkoxide to the base material." The base material is not

involved in the process by which the titania solution is obtained. Instead, the base material is dipped into the titania solution for “titania solution treatment” during the process by which titania gel is formed on the surface of the base material. The present claim amendments resolve any grammatical or organizational ambiguities that may have led to this improper interpretation.

*Rejection under 35 U.S.C. § 103(a)*

The Office Action rejected Claims 1-16 as being unpatentable over JP 2002-248163 (JP '163). Although it was acknowledged that JP '163 does not teach the use of titaniumtetraalkoxide as the titanium component, the Office Action concluded that the presently claimed product is the same as the product disclosed in the reference.

The claimed titanium oxide-organic polymer composite material for artificial bone is materially different than the compound in JP '163. JP '163 teaches that the titanium source is ammonium hexafluoro titanate ( $(\text{NH}_4)_2\text{TiF}_6$ ). When an aqueous solution containing a fluoride ion is used in the process, highly toxic fluorine is present in the produced titanium oxide, and this makes the compound undesirable for use as artificial bone. This fact is evidenced by the attached reference: “Semi-conducting properties of titanium dioxide surfaces on titanium implants,” BIOMATERIALS, 2009; 30: 4471-4479 (Petersson *et al.*). Petersson *et al.* is submitted as background art to provide clear evidence of the differences between the JP '163 compound and the claimed compound. Petersson *et al.* discusses the interaction between titanium dioxide and fluoride ions on the surface of the base material for surfaces treated with hydrofluoric acid. See Section 3.4. JP '163 teaches that hydrofluoric acid may be used in preparing the fluorotitanium complex compound at paragraph [0008]. The surface reactions are analogous to

reactions in solution. *See* Petersson *et al.* at Section 3.4. Figure 7 of Petersson *et al.* clearly shows that fluoride ions are absorbed on oxide surfaces. In contrast, the product of the present invention is defined by the process steps which recite use of titaniumtetraalkoxide. Hence, the presently claimed product does not and cannot contain fluorine, because the recited titanium source contains no fluoro- compounds. The claimed product is thus necessarily different in composition from the product of JP '163.

The Office Action rejected Claims 1-16 as being unpatentable over WO 02/089864 (Kokubo *et al.*) in view of U.S. 4,190,689 (Fujita *et al.*). As a basis for the rejection, the Office Action alleged that the claimed product is the same as the product produced by Kokubo *et al.*

In this case, the present specification teaches unexpected results when the claimed base materials are used to make the claimed composite material, as compared to the composite material made using EVOH as the base material, as in Kokubo *et al.* Page 3 of the specification teaches that the titanium oxide layer formed in the present invention is more suitable for artificial bone, because it has high bioactivity and high resistance to peeling, which is confirmed by the "removing test" discussed on page 9. Therefore, the claimed compound has materially different physical characteristics than that of Kokubo *et al.* that make it more suitable for use as artificial bone.

The cited references also fail to teach that the claimed base material is composed of a polymer compound selected from a group consisting of polyester and nylon. When the incentive to combine the teachings of the references is not immediately apparent, the burden is on the Patent Office to provide some reasonable explanation why the combination of the teachings is

proper. *Ex parte Skinner*, 2 PQ.2d 1788 (BPAI 1986). Here, the Office Action's combination of Kokubo *et al.* with Fujita *et al.* is based on the allegation that Fujita *et al.* teaches the production of polymeric-shaped articles and that artificial bone is such an article. However, there is no indication that one of ordinary skill in the art of the present invention would be motivated to use the teachings of Fujita *et al.* The technical field of Fujita *et al.* is different from that of the present invention, because the polymeric-shaped articles of Fujita *et al.* are not used for materials similar to artificial bone but instead are used for materials suitable for use as film, such as microfilm or overhead projector film. Furthermore, the claims in Fujita *et al.* use means-plus-function language, where the article comprises "means for increasing the slip characteristics of said article without causing any significant increase in the haze of said article." Such transparency and slip characteristics are not disclosed in the present application as a reason for treating the polymer base materials with titania solution. Fujita *et al.* thus teaches away from the present invention.

The conclusion that there is sufficient motivation to combine the references because artificial bone is a "shaped article" is made with impermissible hindsight. The phrase, "polymeric-shaped articles," encompasses a wide scope of materials that may or may not have any relationship to artificial bone. The teaching of Fujita *et al.* is simply that the disclosed polymers, when treated with titanium compounds, create articles that are suitable for film materials. There is no teaching or suggestion that the teachings of Fujita *et al.* could be applied to a vastly different technical field, *i.e.*, to the process of making artificial bone in Kokubo *et al.* Hence, the *prima facie* case of obviousness has not been established.

Response to Office Action of 6/30/2009  
Atty Docket No. TAN-357  
Kokubo *et al.*

Conclusion

In light of the foregoing, it is submitted that the application is now in condition for allowance. It is therefore respectfully requested that the rejections be withdrawn and the application passed to issue.

Respectfully submitted,  
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